

CLINICAL PHARMACY SERVICES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides specific direction, guidance, and procedures related to clinical pharmacy services.

2. SUMMARY OF CONTENT: This is a new Handbook that:

- a. Provides procedures and direction for decision making and program development related to clinical pharmacy practice.
- b. Updates and modernizes policy related to clinical pharmacists with a scope of practice, provides guidance in greater clarity for clinical pharmacy professional practice elements, and is designed to minimize variances in application of clinical pharmacist scope of practice elements across the enterprise.
- c. Provides guidance related to pharmacy professional practice, staffing models, clinical pharmacy workload, and Pharmacy Benefits Management (PBM) Services support.
- d. Standardizes policy requirements for clinical pharmacist scope of practice and oversight by the Executive Committee of the Medical Staff and processes aligned with facility bylaws.
- e. Ensures the Chief of Pharmacy Services has oversight for professional practice for all clinical pharmacists within the facility. This includes, but is not limited to, competency assessment, functional statements, patient care responsibilities, scope of practice recommendations, and professional practice evaluations for clinical pharmacists with a scope of practice. This oversight is shared with the clinical service chief in those instances where the clinical pharmacist with patient care responsibilities is organizationally aligned with another service; in that circumstance, the lead is held by the clinical service chief who ultimately is responsible for the care being delivered in the service area.
- f. Amendment dated June 29, 2017: Updates processes and procedures in addressing a clinical concern for clinical pharmacists with a scope of practice.

3. RELATED ISSUES: VA Handbook 5005/55, Part II, Appendix G15, VA Handbook 5013, VA Handbook 5021, VHA Handbook 1100.19, VHA Handbook 1108.05, and VHA Directive 1108.06.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (PBM) Services (10P4P) in the Office of Patient Care Services (10P4) is responsible for the content of this Handbook. Questions may be addressed to 202-461-7326.

5. RESCISSIONS: VHA Directive 2008-043, dated August 7, 2008, VHA Directive 2009-014, dated March 12, 2009 and VA Manual M-2, Clinical Affairs, Part VII, Chapter 12, paragraphs 12.01 – 12.06, dated October 5, 1994 are rescinded.

6. RECERTIFICATION: This VHA Handbook is scheduled for recertification on or before the last working day of July 2020.

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CLINICAL PHARMACY SERVICES

1. PURPOSE: This Veterans Health Administration (VHA) Clinical Pharmacy Services Handbook provides procedures for the consistent, safe, effective, and efficient delivery of clinical pharmacy services within VHA. This Handbook provides direction for decision making and program development related to clinical pharmacy practice. It provides oversight inclusive of clinical pharmacy practice elements and expectations, professional practice components, staffing models, workload and billing, professional commitment expectations, quality assurance and Pharmacy Benefits Management (PBM) support. Clinical pharmacy practice concepts and models of care reflect evidence-based practice to ensure professional practice meets or exceeds VHA needs. **AUTHORITY:** 38 U.S.C. 7301, 7401, and 7402.

2. BACKGROUND:

a. The evolution of clinical pharmacy practice across the Department of Veterans Affairs (VA) health care system is consistent with the Under Secretary for Health's vision of reducing variability, improving efficiency, and engaging in reliable processes to achieve consistent outcomes. Clinical pharmacy services provided by clinical pharmacists have demonstrated favorable effects across various patient outcomes, health care settings, and disease states. Pharmacists generally have been recognized as one of the most accessible and trusted healthcare professionals for decades, according to Gallup Polls. For over 40 years, clinical pharmacists have practiced comprehensive medication management and provided cognitive clinical pharmacy services. VA has a long history of including clinical pharmacist in all clinical settings to assist providers and patients with management of medications. VA set national policy for the advanced roles of clinical pharmacists authorized to prescribe medications in 1995. These advanced roles continued to be expanded as more VA providers and senior VA leadership have recognized the value that clinical pharmacists bring to VA health care. There is a growing body of evidence and scientific publications that demonstrates the value and impact of integrating clinical pharmacists into a variety of health care settings. In a comprehensive review published by the American College of Clinical Pharmacy in 2008, that included reports reflecting VA settings, it was demonstrated that for every \$1 invested in clinical pharmacy services, more than \$4 in economic benefit is seen.

b. Section 7402 of Title 38 United States Code (U.S.C.) authorizes the appointment of VHA health care providers, including clinical pharmacists, and lists general qualifications by type of provider. The established qualifications and credentialing requirements for employment for clinical pharmacists are addressed in VA Handbook 5005/55, Part II, Appendix G-15, VA Pharmacist Qualification Standards; VHA Directive 2012-030, Credentialing of Health Care Professionals, or subsequent policy issue; and VHA Handbook 1100.19, Credentialing and Privileging.

c. Clinical pharmacist scope of practice includes collaborative medication management, which entails collaborating agreements between physicians or other independent practitioners and clinical pharmacists wherein clinical pharmacists may perform some or all facets of comprehensive medication management. This may

include the authority to prescribe (to include the ability to initiate, modify, continue, and discontinue) medication regimens, order related laboratory tests and diagnostic studies, perform physical measurements and objective assessments, and other necessary actions to facilitate patient care. Such collaborative medication management was first introduced by the Indian Health Service in the 1960s. Collaborative medication management now occurs in a variety of settings, including Accountable Care Organizations, hospitals, ambulatory clinics, and private physician practices. State legislation and regulations authorizing clinical pharmacists to engage in some form of collaborative medication management have facilitated that expansion, with nearly all states having established formal collaborative care agreements for medication management.

d. Clinical pharmacists are valuable resources in VHA. Clinical pharmacists with a scope of practice have a unique role within VA's patient-centered care model due to their extensive experience in managing complex medication regimens used in the treatment of the most common chronic disease states. They work collaboratively within the health care system, serving as medication experts to assist primary care and specialty care teams in meeting the medication therapy needs of their patients. Clinical pharmacists with a scope of practice function as health care providers with a high level of autonomy and exercise independent decision-making within their scope of practice, although clinical pharmacists are not independent practitioners. Historically within VHA, the role and involvement of the supervising physician in the clinical pharmacist's clinical activities varied depending on the clinical pharmacist's practice setting, the nature of the clinical activity, and the working relationship established with the physician. Currently, it is common for clinical pharmacists to work with multiple physicians, teams, and panels of patients simultaneously in their role of comprehensive medication management. Therefore, the current structure for oversight by a single supervising physician does not fit the clinical pharmacy practice model used in VHA today. This Handbook reconciles actual practice with published policy by ensuring the clinical pharmacist with a scope of practice is aligned with staffing procedures contained in the facility bylaws. This further strengthens and supports the role of the clinical pharmacist with a scope of practice as an advanced practice provider and recognizes that a clinical pharmacist works with multiple providers, not just a single physician or provider, consistent with the practices of other prescribers in VHA.

3. DEFINITIONS:

a. **Clinical Pharmacist.** A clinical pharmacist is the full performance level pharmacist position. For purposes of this Handbook the term clinical pharmacist encompasses all licensed pharmacists assigned to positions described in VA Pharmacist Qualification Standards, VA Handbook 5005. This does not include pharmacists serving in a developmental capacity at the General Schedule (GS)-11 grade level. The role of each clinical pharmacist may differ based on their assignment and must be delineated in their functional statement or scope of practice, as appropriate.

b. **Clinical Pharmacist with a Scope of Practice.** A clinical pharmacist with a scope of practice is a clinical pharmacist who provides direct patient care and functions at the highest level of clinical practice, working with a high level of autonomy and independent decision-making within the parameters of their scope of practice, as defined by the individual medical facility, and performs functions as described in paragraph 14. A clinical pharmacist with a scope of practice includes the clinical pharmacy specialist, however a scope of practice may be included in the responsibilities of all levels of clinical pharmacists depending on their assignment as outlined in VA Pharmacist Qualifications Standards, VA Handbook 5005.

c. **Collaborative Medication Management.** Collaborative medication management entails collaborating agreements between physicians or other independent practitioners and clinical pharmacists with a scope of practice wherein clinical pharmacists are permitted to perform some or all facets of comprehensive medication management, within the parameters of their scope of practice. The agreement may include the authority to initiate, modify, and continue medication regimens, order related laboratory tests and diagnostic studies, perform physical measurements and objective assessments, take independent corrective action for identified drug-induced problems and order consults (e.g., dietician, social work, specialty provider), as appropriate, to maximize positive drug therapy outcomes.

d. **Comprehensive Medication Management.** Comprehensive medication management is defined as the standard of care that ensures each patient's medications (VA, non-VA, herbal, alternative, and over the counter medications) are individualized and optimized for the patient based on the patient's medical conditions; comorbidities; individualized patient parameters, such as age-related changes in pharmacokinetics and pharmacodynamics of medications; and patient-centered care factors. It includes the management of chronic diseases, the acute manifestations of these processes, and management of adverse events or reactions to medications. Comprehensive medication management includes components of medication therapy management but is a broader term that encompasses a larger spectrum of services that is provided by clinical pharmacists with a scope of practice. It takes into account drug-food interactions, drug-drug interactions, and drug disease interactions. It includes a patient-specific therapeutic plan, goals, and monitoring to ensure the best possible outcomes. In addition, the patient understands, agrees with, and is an active partner in the plan development and the patient's clinical outcomes.

e. **Independent Practitioner.** An independent practitioner is any individual permitted by law (the statute that defines the terms and conditions of the practitioner's practice in the state of licensure) and the VA medical facility to provide patient care services independently, i.e., without supervision or direction, within the scope of the individual's license and in accordance with individually granted clinical privileges. This is also referred to as a licensed independent practitioner (LIP).

f. **Medication Therapy Management.** Medication therapy management is a distinct service, or group of services, that optimizes therapeutic outcomes for individual patients. These services are performed by clinical pharmacists and focus on a specific patient population and the five core elements of the medication therapy review: personal

medication record, medication-related action plan, intervention and/or referral, and documentation and follow-up.

g. **Pharmacist Mentorship.** A mentorship is an optional period of training and observation in which a currently employed clinical pharmacist is assigned a “mentor” to provide additional training to develop the necessary competencies for new or expanded clinical functions. A mentorship is not required for all clinical pharmacists with a scope of practice. A mentorship is individualized for the clinical pharmacist based on their identified needs and must meet the requirements as outlined in Appendix C of this Handbook.

h. **Pharmacy-Managed Clinics.** Pharmacy-managed clinics are those in which clinical pharmacists provide patient care to Veterans. There are two basic types of pharmacy-managed clinics, those with an educational focus (e.g., new patient orientation clinics, patient education clinics) and those in which focus on comprehensive medication management. The role of each clinical pharmacist functioning in pharmacy-managed clinics will differ based on their assignment and must be delineated in their functional statement or scope of practice, as appropriate.

i. **Professional Practice Evaluation.** All clinical pharmacists with a scope of practice must participate in a professional practice evaluation program. Professional practice evaluations are essential to confirm the quality of care delivered. There are a number of activities that could be included in the professional practice evaluation program including, but not limited to direct observation, clinical discussion, and clinical care (or pertinence) reviews. The information collected must be provider specific, reliable, easily retrievable, timely, justifiable, comparable, and risk adjusted where appropriate. The professional practice evaluation program includes both ongoing professional practice evaluations and focused professional practice evaluations as described in paragraph 17 of this Handbook.

j. **Scope of Practice.** A scope of practice, as part of collaborative medication management, includes the clinical pharmacist’s medication prescriptive authority, as well as a description of routine and non-routine duties to be performed, expectations, and the general areas of responsibility as outlined in paragraphs 10 and 14 of this Handbook. The scope of practice permits a high level of autonomy and independent decision-making when performing the authorized duties but requires collaboration with the healthcare team for the overall care of the Veterans. In performing the authorized duties, the clinical pharmacist is responsible and accountable for the patient care managed under the clinical pharmacist’s scope of practice. To be granted prescriptive authority and responsibility, the clinical pharmacist must have experience and expertise in the practice areas and functions, including, but not necessarily limited to, medication management of patients with defined diagnoses, management of medication-related adverse events, ongoing and acute medication monitoring, and collaboration with other healthcare providers for management of new diagnoses. Clinical pharmacists may dispense, prescribe, and administer controlled substances only if they are authorized by their State license to do so and comply with the limitations and restrictions on that

authority. A scope of practice may be included in the responsibilities of all levels of clinical pharmacists depending on their assignment.

4. SCOPE: Clinical pharmacy services are integral to VHA's comprehensive health care initiatives. Maximizing the comprehensive medication management capabilities of the clinical pharmacist and fully integrating clinical pharmacy services into all team-based models of care can significantly improve access and quality of patient care. It is imperative that clinical pharmacists with a scope of practice, as part of collaborative medication management have the ability to perform physical assessment; hold prescriptive authority; order, interpret, and monitor laboratory results; develop patient-centered therapeutic plans; and manage acute and chronic disease states and processes in which medications are the primary treatment. This Handbook governs the development and maintenance of clinical pharmacy services in VHA.

5. RESPONSIBILITIES:

a. **Veterans Integrated Service Network Pharmacist Executive.** The Veterans Integrated Service Network (VISN) Pharmacist Executive (VPE), or designee, is responsible for:

(1) Facilitating coordination and standardization of clinical pharmacy activities and practices within the VPE's assigned VISN.

(2) Ensuring that core concepts and principles of clinical pharmacy are clearly communicated and promoted within the VISN.

(3) Ensuring that clinical pharmacy staffing models are evaluated regularly for all VA medical facilities within the VISN based on the needs of the facility, complexity, size, and clinical programs available, and discussing with leadership, as appropriate.

(4) Ensuring that clinical pharmacy practice issues are afforded the same priority as operational, formulary, and medication safety issues in each VISN.

(5) Serving as an advisor to the facility Chiefs of Pharmacy Services regarding the expansion of clinical pharmacy programs through changes in policies, creation of performance goals, streamlining operational activities, and using systems redesign principles to drive improvements in patient care.

(6) Developing and coordinating a mechanism for communication, dissemination, and discussion of clinical pharmacy practice issues as described in paragraph 9 of this Handbook.

(7) Coordinating communication and required actions from the facility Chiefs of Pharmacy, as required, regarding clinical pharmacy practice issues identified at the facility or VISN level by PBM.

(8) Participating regularly in calls with PBM to communicate VISN perspectives and share best practices related to clinical pharmacy practice.

b. **VA Medical Facility Director.** The VA medical facility Director is responsible for ensuring that:

(1) The clinical pharmacist with a scope of practice is provided the same level of consistent support staff support (e.g., appointment management support, vital signs) given to other providers when the clinical pharmacist is providing direct patient care.

(2) The Chief of Pharmacy Services is recognized by and has authority to provide recommendations related to clinical pharmacist scope of practice and professional practice to the Executive Committee of the Medical Staff (ECMS).

(3) In those instances where the clinical pharmacist positions are aligned within a service, (e.g., Primary Care, Specialty Care, Pain Management), both the clinical service chief to which the clinical pharmacist is aligned and the Chief, Pharmacy Service will approve recommendations for appointment and scopes of practice (i.e., there will be two service chief recommendations).

(4) When appropriate, the clinical pharmacist with a scope of practice is provided adequate space in close vicinity to the teams the clinical pharmacist supports.

(5) The following, related to clinical pharmacist scope of practice, occur:

(a) Written local policies, consistent with this Handbook, are established governing scopes of practice for clinical pharmacists with patient care responsibilities.

(b) A scope of practice with prescriptive authority, consistent with paragraphs 10, 11 and 12 of this Handbook, is in place for each VHA clinical pharmacist with patient care responsibilities as outlined in paragraph 14 of this Handbook.

(c) The Chief of Pharmacy Services, and clinical service chief of alignment, as applicable, provide oversight of the clinical pharmacist's professional practice evaluation process for all clinical pharmacists with a scope of practice as outlined in paragraph 17 of this Handbook.

(d) The relevant credentials of each clinical pharmacist are verified in accordance with VHA Handbook 1100.19 and VHA Directive 2012-030, or subsequent policy issue.

(e) Clinical pharmacists with a scope of practice only prescribe controlled substances if authorized by the VA medical facility and the state of licensure (i.e., the statutes and regulations that defines the terms and conditions of the clinical pharmacist's license) and they perform this function in accordance with Federal law and regulations and VHA policy.

NOTE: *The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 defines requirements for the prescription of controlled substances (Schedules I through V as defined under the Controlled Substances Act) via telemedicine. Questions regarding the authority under the Ryan Haight Act should be directed to VHA TeleHealth Services at <http://vawww.telehealth.va.gov/about/contact.asp>. This is an internal VA Web site that*

is not available to the public. All prescribers of controlled substances must ensure compliance with the regulations of this Act and all applicable federal laws and VHA policy.

(f) Clinical pharmacists with a scope of practice comply with the limitations and restrictions on that authority.

(g) Inpatient orders and outpatient prescriptions outside of the clinical pharmacist's established scope of practice are signed by an authorized prescriber involved with the patient's care prior to being filled.

c. Chief of Pharmacy Services.

(1) The Chief of Pharmacy Services, or designee, has primary responsibility for operation of the inpatient and outpatient pharmacy areas in addition to clinical pharmacy services provided at the facility. The Chief of Pharmacy Services must identify the best use of pharmacy resources and staff through process improvement activities, emphasizing evolving clinical pharmacist and technician roles. This includes the use of automation, identification of key roles for pharmacy technicians, and opportunities to expand medical facility policy with safe medication practices, to augment the assignment of clinical pharmacists to patient care activities (as outlined in paragraph 10 of this Handbook).

(2) The Chief of Pharmacy Services is responsible for oversight of professional practice for all clinical pharmacists within the facility, regardless of the organizational structure of the clinical pharmacists or service. This includes, but is not limited to, competency assessment, functional statements, patient care responsibilities, scope of practice recommendations, and professional practice evaluations for clinical pharmacists with a scope of practice. This oversight is shared with the clinical service chief in those instances where the clinical pharmacist with patient care responsibilities is organizationally aligned with another service, with the lead being held by the clinical service chief who is ultimately responsible for the care being delivered in the clinical service.

(3) The Chief of Pharmacy Services is responsible for ensuring:

(a) Pharmacy Service has oversight of the medication management process at the VA medical facility level.

(b) Development of medical center policies, performance goals and monitors, and standardization of clinical pharmacy practice, as appropriate, that support clinical pharmacy services.

(c) Clinical pharmacy practice and policy issues are communicated to the VPE, facility leadership, and the PBM Clinical Pharmacy Practice Office (CPPO).

(d) Clinical pharmacy workload and billing data is reported to the medical facility Director and VPE as appropriate.

(e) Development of VA medical facility policy to allow clinical pharmacists to perform therapeutic substitutions of key medications or other activities as appropriate (as outlined in paragraph 15 of the Handbook).

(f) The following, related to the clinical pharmacy practice at the VA medical facility level, occur:

1. When the clinical pharmacist is providing patient care under a scope of practice and functioning as an advanced practice provider, pharmacy services such as routine inpatient and outpatient pharmacy prescription processing activities should be provided by other clinical pharmacists, as appropriate.

2. Clinical pharmacy staffing models are evaluated at least annually, based on the needs of the facility, complexity, size, and clinical programs available and are discussed with leadership, as appropriate. **NOTE:** *This includes a review of clinical pharmacy encounter workload reports to ensure that patients have access to clinical pharmacy services.*

3. Clinical pharmacists have access to the appropriate databases and tools, as appropriate, to perform population management to identify high-risk patients in need of medication management services.

4. Pharmacy resources and staff are managed through process improvement and systems redesign which emphasizes both the clinical pharmacist and technician roles working at the top of their licenses and training.

(g) The following, related to clinical pharmacist professional practice, occur:

1. Scope of practice statements for clinical pharmacists are standardized throughout the facility for individuals with similar areas of responsibilities as described in Appendix B of this Handbook.

2. All clinical pharmacists with a scope of practice participate in a professional practice evaluation program outlined in paragraph 17 and results are reviewed in accordance with the VA medical facility policy.

3. VA medical facility policy is developed to outline requirements for clinical pharmacist professional practice evaluations (ongoing and focused), including mentorship requirements (see paragraph 16.a. of the Handbook), for all clinical pharmacists with a scope of practice.

4. Clinical pharmacists with a scope of practice do not verify, check, or release any medication order that they themselves have prescribed. **NOTE:** *Regular review and audit to evaluate this practice must be performed on an ongoing basis.*

5. All clinical pharmacists with patient care responsibilities document workload in accordance with VHA policy and guidance.

6. Pharmacy clinics are designed appropriately and are in accordance with VHA policy and guidance.

7. VA medical facility policy is developed to outline appropriate referral to pharmacy-managed clinics, as well as procedures for clinical pharmacist's referral to higher levels of care.

8. A mechanism for communication, dissemination, and discussion of clinical pharmacy practice issues as described in paragraph 9 of this Handbook, are developed and coordinated.

9. There is appropriate integration of pharmacy residents and students into clinical pharmacy programs.

10. An annual review of Person Class Codes (PCC) is performed for all clinical pharmacists and technicians, to include updating when new employees enter the service and changes in board certifications or scope of practice occur.

11. Responsibilities related to the clinical pharmacy practice are streamlined.
NOTE: Typically this assignment would be at that level of the Associate Chief for Clinical Pharmacy Services.

12. All clinical pharmacists with a scope of practice must be entered and updated quarterly into the PBM Clinical Pharmacy Scope of Practice SharePoint site at: (<http://vawww.infoshare.va.gov/sites/ClinicalPharmacy/Lists/Clinical%20Pharmacists%20with%20Scope%20of%20Practice/AllItems.aspx>). **NOTE:** This is an internal VA Web site and is not available to the public. This site should be audited at regular intervals by the Chief of Pharmacy Services (or designee).

d. **Clinical Pharmacists.**

(1) All clinical pharmacists are encouraged to work at the top of their licenses, competency, and scope of practice. All clinical pharmacists must have functional statements that accurately reflect the job responsibilities and, where appropriate, scopes of practice that define the tasks performed. Functional statements must describe expectations of the job performance, in addition to the duties and role of the individual within the context of the pharmacy or practice area. Functional statements must be coupled with a competency assessment that describes practice area specific requirements. The functional statements of the clinical pharmacist serve as the basis for ensuring the individual is functioning at the top of their licensure and scope.

(2) The clinical pharmacist has an irreplaceable role as the medication expert due to their extensive knowledge of medications, clinical pharmacology, pharmacokinetics, pharmacodynamics, and therapeutics; this is a combined skill set that is unique to this group of health care professionals. Resources should be dedicated to clinical pharmacy services at each VA medical facility. These services may include, but are not limited to:

(a) Designing, implementing, assessing, monitoring, and documenting therapeutic plans utilizing the most effective, safest, and economical medication treatments.

(b) Helping achieve positive patient-centric outcomes and providing clinical pharmacy expertise through direct and indirect interactions with patients, providers, and interprofessional teams in assigned areas.

(c) Performing the physical measurements and objective assessments necessary to ensure the patients appropriate clinical responses to drug therapy.

(d) Ordering laboratory and other diagnostic studies necessary to monitor, support, and modify the patient's drug therapy.

(3) All clinical pharmacists are responsible for ensuring that:

(a) They provide comprehensive medication management services, as appropriate and in accordance with their functional statement or individual scope of practice.

(b) They work collaboratively with other health care professionals to enhance the provision of care to Veterans.

(c) They function at the highest level of professional pharmacy practice within the parameters of their functional statement or scope of practice and assume accountability for their patient care outcomes.

(d) They document patient care encounters appropriately and in compliance with VHA policy and guidance for all inpatient and outpatient patient-specific consultations that meet the intent of an encounter (e.g., medical history taken, clinical decision making, and documentation).

(e) They solve medication-related problems, and coordinate and organize responsibilities to maximize outcomes in their practice area or area of clinical expertise.

(f) They seek opportunities to participate and publish, as appropriate, their role in the pharmacy practice model; evidence-based research (as available); clinical reviews of literature; drug information topics; and quality improvement projects that demonstrate improved patient care outcomes.

(g) They are actively involved and integrated into training programs of pharmacy students and residents, allied health professionals, as well as other health care professionals available at the local VA medical facility level, as applicable.

6. PATIENT CARE ACTIVITIES: Patient care activities include activities in which the clinical pharmacist is working directly or indirectly with the health care team and patient. These activities are not limited to face-to-face patient care encounters but encompass a variety of modalities and professional responsibilities. Patient care activities are included in the role of all clinical pharmacist positions, as appropriate. The role of each clinical pharmacist may differ based on their assignment and must be delineated in their

functional statement or scope of practice as appropriate (see paragraphs 14 and 15 of this Handbook). Patient care activities include, but are not limited to:

- a. Face-to-face comprehensive medication management of patients.
- b. Same day face-to-face patient visits (such as patient medication reviews for comprehensive medication management, recent hospital discharges, and dual care management).
- c. Virtual care modality visits, such as: Veteran requests through secure messaging, telephone-based care, clinical video telehealth, and Home Telehealth.
- d. Shared medical appointments or group education clinics.
- e. Team or interdisciplinary patient care rounds or meetings.

7. ROLES FOR PHARMACY TECHNICIANS: The pharmacy technician has specific knowledge of the medication use process within VHA and integral to pharmacy operations as outlined in VHA Handbook 1108.05, Outpatient Pharmacy Services, and VHA Directive 1108.06, Inpatient Pharmacy Services. Accordingly, pharmacy technicians can assist with many of the technical issues associated with comprehensive medication management. Under the supervision of a clinical pharmacist, the pharmacy technician may serve the pharmacy team in the following activities including, but not limited to:

- a. Obtaining medication histories to assist with medication reconciliation.
- b. Patient education related to VA formulary status of medications.
- c. Documenting medication adherence.
- d. Documenting patient allergies and adverse drug reactions.
- e. Patient education on navigating the VA Pharmacy (including patient management of refills and renewals, important telephone numbers for pharmacy issues, etc.).

8. REFERRALS FOR CARE:

a. Clear and standardized processes for referral of patients to pharmacy-managed clinics must be established at the VA medical facility level. The method of referral may differ based on the role of the clinical pharmacist within the specific practice area. The referral method may include standardized templates (e.g., formal chart consults), collaborative care agreements (formerly known as service agreements), referral of patients from providers or team members through email communication, team or interdisciplinary meetings, clinical chart consults, and population management databases (e.g., clinical dashboards). In addition, patients may be referred, as deemed appropriate, through identification from a medication use evaluation conducted nationally, VISN-wide, or at the local medical facility. The referral method ensures that the appropriate patient is referred to the pharmacy for management.

b. The referral method must include a method of notifying the provider or team when care has been completed by the clinical pharmacist to ensure care coordination. This method may differ based on the role of the clinical pharmacist in the practice area. In most instances it will be appropriate to refer back to the provider or team once the goals have been achieved as measured by evidence-based guidance or patient disease parameters. The clinical pharmacist will continually work with providers to identify when medication therapy is no longer indicated for individual patients. For all patients who have been referred to pharmacy-managed clinics and are under the care of a clinical pharmacist with a scope of practice, guidance for discharge should be established for patients who frequently miss visits, fail to follow instructions, or continue to demonstrate poor medication adherence despite intensive efforts.

c. Infrastructure must exist for a clinical pharmacist with a scope of practice to refer patients to higher levels of care when appropriate. Policy must outline what referrals are appropriate to be made by the clinical pharmacist with a scope of practice. Some examples include, but are not limited to, referrals for routine care or assessment to clinical nutrition professionals, prosthetics, social workers, integrated mental health professionals, or other specialty areas. The clinical pharmacist must communicate with the collaborating provider(s), or referring provider as appropriate, in cases when patient assessment requires a referral to higher levels of care. Most clinical pharmacists with a scope of practice provide patient care across multiple teams, teamlets, or patient panels; therefore, it is imperative that a relationship and communication infrastructure exists with the collaborating provider(s) for continuity of care. The collaborating provider provides management and consultation to the clinical pharmacist when referrals to higher levels of care are unclear or patients require additional assessment that is outside of the scope of practice and expertise of the clinical pharmacist. In addition, the clinical pharmacist with a scope of practice communicates with the collaborating provider when any significant changes in the patient's conditions occur. In some circumstances (e.g., such as in Patient Aligned Care Team (PACT)), the original referring provider is considered the collaborating provider. In other circumstances, such as when a clinical pharmacist practices in the specialty care area, the collaborating provider may be the specialty care provider. Referrals to higher levels of care include mechanisms for triaging urgent and acute cases (e.g., referral to urgent care or emergency department in patients with worsening of symptoms) and means for communication and care coordination when patient referrals are performed.

d. A clinical chart consultation, including an E-consult, may be provided by a clinical pharmacist in response to a formal request from a provider seeking opinion, advice, or expertise regarding medication management of a specific patient (e.g., E-Consults, clinical pharmacy chart consults) as outlined in VHA Directive 1232, Consult Processes and Procedures, or subsequent policy issue. Utilizing information provided in the consult request and/or review of the patient electronic medical record, the responding clinical pharmacist provides a documented response in the computerized patient record system (CPRS) consult functionality that addresses the request. E-consults can be used in the outpatient or inpatient setting. The consultation activity must be within the functional statement or defined scope of practice of the clinical pharmacist responding to the consultation, as appropriate.

(1) E-consults are recommended to be used in the following clinical pharmacy practice situations:

NOTE: *E-Consults should only be used to capture clinical workload which includes a medical history, clinical decision making, and documentation.*

(a) Situations in which medication management advice is needed for a single episode of care.

(b) As a means to assist providers by addressing a clinical problem or question related to medication management when a face-to-face visit is not required, such as opinion related to a patient specific medication management issue, disease state or therapy specific questions, titration or taper of medications, and one-time therapeutic drug monitoring.

(c) In areas where pharmacy staff is limited (i.e., CBOCs and pharmacy-managed clinics with access issues).

(d) When a medication management question or advice is needed from one provider to a clinical pharmacist (e.g., PACT physician to PACT clinical pharmacist, PACT clinical pharmacist to a pain management clinical pharmacist, or physician to an Infectious disease clinical pharmacist).

(e) When a medication management question or advice is needed from a clinical pharmacist at another facility who provides expertise for the entire VISN. The clinical pharmacist providing the teleconsultation services must be credentialed and authorized by a scope of practice to provide that care. The policy and procedures for credentialing for teleconsultation are contained in VHA Handbook 1100.19.

(2) An E-consult should not to be used in the following clinical pharmacy practice situations:

(a) Non-formulary or restricted drug consults.

(b) Patients with a need for ongoing medication monitoring, (e.g., such as clozapine monitoring, antimicrobial stewardship monitoring programs, or anticoagulation monitoring).

(c) Home Based Primary Care (or similar) chart reviews.

(d) Clinical interventions originating from a dashboard reviews.

9. CLINICAL PHARMACY PRACTICE COUNCIL:

a. It is essential that a communication conduit exists for clinical pharmacy practice issues and sharing of strong practices across VHA. A Clinical Pharmacy Practice Council (CPPC) is a way to provide a conduit for bi-directional communication. The CPPC provides alignment of integral clinical pharmacy professional practice elements, a conduit for communication between the PBM CPPO, VISNs, and facilities on clinical pharmacy practice issues, and as a source to identify strong practices for sharing

system-wide. The CPPC functions to assist pharmacy leaders in ensuring proper alignment of clinical pharmacy practice components. Facilities and VISNs should have a mechanism for communication, dissemination, and discussion of clinical pharmacy practice issues. VA medical facilities and VISNs can determine the “best” way to ensure the principles of the CPPC are encompassed in their committees or workgroups. In addition to facility- and VISN-level CPPCs, a national CPPC exists to provide recommendations and guidance related to clinical pharmacy practice oversight issues. More information on the CPPC can be found on the Clinical Pharmacy SharePoint at the following link:

<http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Clinical%20Pharmacy%20Practice%20Council.aspx>. **NOTE:** This is an internal VA Web site and is not available to the public.

b. The goal of the CPPC is to create a clinical pharmacy community of practice that serves as a conduit and advisory panel to share strong practices and assist in the implementation of standardized practices, policies, and programs that enhance clinical pharmacy services.

c. Development of a CPPC accomplishes the following:

(1) Enhancing communication between facilities and the PBM CPPO on projects, policy, initiatives, and guidance (updates or new issues);

(2) Sharing strong practices related to clinical pharmacy practice;

(3) Assessing clinical pharmacy outcomes and workload to include review of clinical pharmacy workload information, providing direction on the appropriate capturing of pharmacy workload, clinical pharmacy interventions and return on investment for clinical pharmacy services;

(4) Evaluating clinical performance metrics and population management databases or dashboards for opportunities for clinical pharmacist involvement to improve access and quality of patient care;

(5) Identifying gaps that may exist in patient care with emphasis on expansion of clinical pharmacy services; and

(6) Ensuring a platform for discussion of clinical pharmacy professional practice elements.

10. CLINICAL PHARMACIST SCOPE OF PRACTICE: A clinical pharmacist scope of practice must meet requirements as outlined in this Handbook. A scope of practice is required for any positions in which the clinical pharmacist has patient care activities outlined in paragraph 14 of this Handbook and serves as an advanced practice provider, as part of collaborative medication management, to initiate, modify, renew, or discontinue medication therapy.

a. The scope of practice, as part of collaborative medication management, allows the clinical pharmacist to function with a high level of autonomy and independent clinical decision-making for activities included in the scope of practice and collaboratively with the health care team for the overall care of the Veteran. The clinical pharmacist is responsible and accountable for the disease states and conditions managed under the clinical pharmacist's scope of practice. Prescribing, administering or dispensing controlled substances may be included in the scope of practice only if the clinical pharmacist is authorized by their state license to do so and complies with the limitations and restrictions on that authority. Prescriptive authority and responsibility defined in the scope of practice is limited to practice areas for which the clinical pharmacist has experience and expertise, to include:

- (1) Addressing medication management needs of patients with defined diagnoses.
- (2) Management of medication-related adverse events.
- (3) Ongoing and acute medication monitoring.
- (4) Collaboration with other health care providers for management of new diagnoses for patients.

b. The following elements must be in place at the VA medical facility level for all clinical pharmacists with a scope of practice:

(1) The medical facility must have policy that addresses all required elements of the scope of practice including, but not limited to:

(a) Requirements of an initial scope of practice (see paragraphs 11 and 12 of this Handbook).

(b) Processes for renewal of an existing scope of practice (see paragraph 13 of this Handbook).

(c) Professional practice evaluations (focused and ongoing) (see paragraph 17 of this Handbook).

(2) All competency assessments, education, training, experience requirements to perform the functions identified in the scope of practice must be reviewed by the Chief of Pharmacy Services prior to submission to the ECMS for review and recommendation to the medical facility Director.

(3) The scope of practice renewal process must be conducted for each clinical pharmacist at least every two years, but prior to the expiration of such scope of practice. This renewal process must coincide with the re-credentialing process of the clinical pharmacist with a scope of practice.

11. REQUIRED ELEMENTS OF A SCOPE OF PRACTICE: Scopes of practice must be standardized across VA medical facilities for clinical pharmacists with similar practice

areas, training, and experience similar to the example outlined in Appendix B. Required elements of a scope of practice include:

- a. The education, training, and experience the clinical pharmacist possesses to perform the functions identified.
- b. The required skills and knowledge that the clinical pharmacist must possess in order to perform the requested functions identified.
- c. The scope of practice statements, individual clinical pharmacist proficiency, and professional practice evaluation results are reviewed, at a minimum, biannually by the ECMS, Chief of Pharmacy Services, and clinical Service Chief (as applicable).
- d. Identifying, as part of collaborative medication management, the clinical pharmacist's prescriptive authority, laboratory, diagnostic and referral responsibilities.
- e. Describing the routine and non-routine professional duties.
- f. Describing the general practice-based areas of responsibility for activities, to include the practice location of the clinical pharmacist (e.g., VA medical facility, CBOCs, contracted locations, Domiciliary, Telemedicine).
- g. Outlining the clinical pharmacist's responsibility for communication with the collaborating physician such as when significant changes in the patient's condition occur, when referrals to higher levels of care are unclear, and advanced patient care management outside of the scope of practice and expertise of the clinical pharmacist is required.

12. PROCEDURES FOR AN INITIAL SCOPE OF PRACTICE: All clinical pharmacists applying for a scope of practice must have appropriate competency assessment of the critical duties outlined in their scope. This ensures leadership can determine their readiness and abilities for their position, as well as providing appropriate orientation to practice, procedures and policy in their practice area. As applicable, the ECMS, Chief of Pharmacy Services, and if appropriate, clinical service chief of alignment, will outline any mentorship requirements to be completed prior to the scope of practice being forwarded for approval (see Appendix C).

NOTE: *A mentorship is an optional period of training and observation in which a currently employed clinical pharmacist is assigned a "mentor" to provide additional training to develop the necessary competencies for new or expanded clinical functions. A mentorship is not required for all clinical pharmacists with a scope of practice. A mentorship is individualized for the clinical pharmacist based on their identified needs and must meet the requirements as outlined in Appendix C.*

- a. Each clinical pharmacist seeking a scope of practice must prepare an application that includes all required elements outlined in paragraph 11 of this Handbook, including mentorship results (as applicable), which have been reviewed and endorsed by the

Chief of Pharmacy and clinical service chief of alignment, prior to submission to the ECMS for review and recommendation to the medical facility Director.

b. After approval of an initial scope of practice, the clinical pharmacist must have a focused professional practice evaluation (FPPE) performed as outlined in paragraph 17.b.(10)(a).

13. RENEWAL OF SCOPE OF PRACTICE: All clinical pharmacists with a scope of practice must participate in an ongoing professional practice evaluation (OPPE) program as outlined in paragraph 17.b. The cumulative results will be used for assessing the appropriateness of renewal of a scope of practice which must be done at a minimum of every two years. Any exemptions to the regular professional practice evaluation requirement should be approved by the Chief of Pharmacy Services and, if the clinical pharmacist is assigned to a clinical service, the appropriate clinical service chief and then presented to the ECMS for review and recommendation to the VA medical facility director. For all other actions in which the clinical pharmacist scope of practice request is denied or not renewed, the reason for denial or nonrenewal must be documented in accordance with facility policy and VA Handbook 5013 or VA Handbook 5021, as applicable, or subsequent policy issue.

14. ACTIVITIES THAT REQUIRE A SCOPE OF PRACTICE: Activities that require a scope of practice as outlined in paragraph 10 include, but are not limited to, the following:

a. Executing therapeutic plans utilizing the most effective, safest, and most economical medication treatments.

b. Ordering, subsequent review and action on appropriate laboratory tests and other diagnostic studies necessary to monitor, support, and modify the patient's drug therapy.

c. Prescribing medications, devices and supplies to include: initiation, continuation, discontinuation, monitoring, and altering therapy.

d. Ordering medications and administering vaccines as necessary for the provision of pharmaceutical care.

e. Taking independent corrective action for identified drug-induced problems.

f. Ordering consults (i.e., dietician, social work, specialty provider), as appropriate, to maximize positive drug therapy outcomes.

g. Obtaining and documenting informed consent for treatments and procedures that require consent for which the clinical pharmacist is responsible, including those where the clinical pharmacist is the prescriber of a treatment that requires consent or when they are providing medication management services on behalf of the original prescriber.

NOTE: *The clinical pharmacist must have sufficient knowledge and training in the*

treatment or procedure, its indications, risk and benefits, complications, and alternative treatments, to effectively counsel the patient.

15. ACTIVITIES THAT DO NOT REQUIRE A SCOPE OF PRACTICE: The following is a list of examples of activities that generally are considered routine clinical pharmacist duties that do not require a scope of practice. All clinical pharmacists can perform duties that are considered routine. However, depending on the nature of the function or the manner in which it is performed, the activities could result in the performance of patient care, requiring a scope of practice.

- a. Participating in all tasks related to medication preparation and dispensing.
- b. Conducting comprehensive appraisals of patients' health status by completing medication histories including patient interviews.
- c. Completing medication reconciliation including updating the medication profile to reflect an accurate, active list of VA and non-VA medications. This may include adding non-VA medications or discontinuing duplicate medications or those the patient is not taking.
- d. Providing oral and/or written communication with other health care professionals regarding drug therapy selection and management. This includes, but is not limited to, assisting with formulary product selection and pharmacokinetic monitoring and dosing.
- e. Monitoring and assessing drug therapy, communicating the findings and any recommendations for medication changes to appropriate clinical providers for final approval, and documenting appropriately in the CPRS.
- f. Providing patient and health care professional education and drug information.
- g. Utilizing all CPRS and pharmacy software functions including: order flags, view alerts, hold functions, and service reject, in accordance with local VA medical facility policy.
- h. Entering supply orders to support medication compliance and accurate medication administration (e.g., syringes, needles, tablet splitters), in accordance with VA medical facility policy.
- i. Managing out-of-stock situations by substituting alternate dosage strengths and instructions of the same medication equal to the prescribed dose and schedule as approved by the Pharmacy and Therapeutics Committee and ECMS. It is imperative that this includes the provision of patient education if the patient will be receiving a different strength or dosage form and the instructions change.
- j. Implementing VA medical facility policies including therapeutic interchanges and automatic substitutions (e.g., Pharmacy and Therapeutics Committee activities).

- k. Participating in medical emergencies including code teams and emergency management activities (with appropriate certification).
- l. Reporting adverse drug events, near misses and medication errors.
- m. Completing non-formulary and medication approval consults.
- n. Coordinating and conducting research in accordance with FDA and VHA guidelines and regulations and in accordance with local VA medical facility policy.
- o. Documenting patient care activities in CPRS (e.g. group education notes, medication reconciliation activities).
- p. Providing patient and healthcare professional education and drug information.
- q. Participating in clinical pharmacy education during shared medical appointments or group visits.
- r. Participating in Antimicrobial stewardship activities outlined in guidance or medical center policy as appropriate (e.g., IV to PO, aminoglycoside monitoring) and providing appropriate action (e.g., recommendations to responsible individuals, therapeutic substitution).
- s. Chart review activities and comprehensive medication management reviews for Community Living Centers, home based primary care, and residential treatment facilities;
- t. Management of safety initiatives and participating in Medication Usage Evaluations and quality assurance oversight.
- u. Participating in and educating Veterans on Dual care activities as defined in VHA Directive 2009-038, VHA National Dual Care Policy, or subsequent policy issue.
- v. Performing population management activities to identify high risk patients and those in need of comprehensive medication management services.

16. PHARMACY RESIDENT SCOPE OF PRACTICE: When determining a scope of practice for a clinical pharmacist, it is important to ensure the individual has the competency to perform the assigned tasks. In addition to the following, a pharmacy resident must meet all required elements for scope of practice as outlined in this Handbook.

- a. **Post-Graduate Year 1 (PGY1).** Pharmacy residents at this level of experience should not be granted prescriptive authority under a scope of practice for use during their residency training program. PGY1 pharmacy residents may still perform functions that prepare them for the role of a clinical pharmacist with a scope of practice, such as entering orders for medications, laboratory tests, and consults under the prescribing preceptor's name for signature. The prescribing preceptor assumes the responsibility for those orders upon signature.

b. **Post-Graduate Year 2 (PGY2).** A PGY2 Residency is generally a second-year residency program or specialized training program that encompasses broader knowledge, skills, and abilities for comprehensive medication management and leadership in a variety of clinical areas.

(1) The PGY2 residency builds upon skills and training obtained during the PGY1 year and seeks to further enhance the knowledge, skills, and abilities (KSAs) in a specific area of emphasis (such as cardiology, oncology, administration, pain management, or other subspecialty areas). It is acceptable to grant a PGY2 pharmacy resident a scope of practice with prescriptive authority, as applicable, if the individual clinical pharmacist meets all elements included in this Handbook; however, VA medical facilities may not require the PGY2 to function under a scope of practice during the residency training program.

(2) It is important that the medical facility consider the following items when determining appropriateness of an individual PGY2 resident for a scope of practice:

(a) The individual's KSAs, training and competence level for the scope of practice.

(b) The individual's readiness and ability to assume a high level of autonomy and decision-making for the duties authorized under the scope of practice.

(c) The benefit to the medical facility and resident in preparing them for higher level clinical practice.

(3) If a scope of practice is granted, these individuals must participate in the same professional practice evaluation programs as other clinical pharmacists with a scope of practice outlined in paragraph 17 of this Handbook. Resident activities, including those outlined in the scope of practice, are to be supervised by the Residency Program Director and the Chief of Pharmacy Services throughout the residency program.

c. **Supervision of Pharmacy Residents.** Supervision of pharmacy residents must be consistent with requirements outlined in VHA Handbook 1400.04, Supervision of Associated Health Trainees. In addition the specific type, intensity, and frequency of supervision are to be determined by an assessment of a combination of factors which include, but are not limited to, education and experience of the resident, and assigned level of responsibility.

17. PROFESSIONAL PRACTICE EVALUATION COMPONENTS:

a. **Competency Assessment.** Competency refers to the quality of having sufficient aptitude, knowledge, skill, and abilities to fulfill the duties and responsibilities of the assigned position. All pharmacy staff providing care, treatment, or services are required to have competencies based on their functional statements and which must be regularly assessed. A competency assessment must occur upon initial appointment and should be ongoing in accordance with the Joint Commission standards. This competency assessment evaluates those clinical pharmacist competencies not included in the pharmacist-specific scope of practice, which are assessed through the professional

practice evaluation programs (OPPE and FPPE) described in paragraph 17.(b). The Chief of Pharmacy Services, or designee, must ensure standardization for the competency assessment process, including documentation of assessments, and competency assessment forms for clinical pharmacists and pharmacy technicians. Only clinical pharmacists with a scope of practice will have OPPE or FPPE performed; therefore, it is important that ongoing competency assessment is in place to ensure all clinical pharmacists are able to meet all standards outlined in their functional statement. An example of a standardized competency assessment can be found on the Clinical Pharmacy SharePoint Site at:

(<http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/PBM%20Position%20Statements/Forms/AllItems.aspx>). **NOTE:** *This is an internal VA Web site and is not available to the public.*

b. **Professional Practice Evaluations.** All clinical pharmacists with a scope of practice must participate in a professional practice evaluation program. The criteria for both the Ongoing and the Focused Professional Practice Evaluation (OPPE and FPPE respectively) process are to be defined in advance, using objective criteria, accepted by the practitioner, recommended by the service chief and ECMS as part of the credentialing process and approved by the medical facility Director. The process may include prospective, concurrent, or retrospective activities and include periodic chart review, direct observation, or discussion with other individuals involved in the care of patients. An evaluation of the patient care provided by the clinical pharmacist with a scope of practice, or clinical care review, is a required component of the professional practice evaluation. Each VA medical facility may decide what items will be required for the professional practice evaluation of a clinical pharmacist with scope of practice encompassing the six general competencies of patient care, medical/clinical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice. Professional practice evaluations and other reviews must, by law, be kept separate from any reviews protected by the quality assurance (QA) regulations. 38 U.S.C. 5705. Professional practice reviews are maintained in accordance with the Privacy Act System of Records Notice 77VA10Q, Healthcare Provider Records. Different types of reviews (e.g., QA protected and management) can occur before, concurrently, or after each other, as long as information collected in a QA protected activity and other reviews (professional practice evaluations, management reviews, etc.) and processes are kept separate. If information from a QA protected review triggers an additional review, the information must be rediscovered through non-QA protected mechanisms. The professional practice evaluation process may include periodic chart review, direct observation, monitoring of patient assessment techniques, or discussion with other individuals involved in the care of patients. Examples of professional practice evaluations can be found on the Clinical Pharmacy SharePoint site at <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/default.aspx>. **NOTE:** *This is an internal VA Web site and is not available to the public.* Results of professional practice evaluations should be included in the discussion of the appraisal as appropriate. The following are required elements of professional practice evaluations:

(1) Prior to the first professional practice evaluation, the clinical pharmacist with a scope of practice should be informed, both verbally and in writing, that documents generated from clinical professional practice evaluation reviews are not protected under 38 U.S.C. 5705, and can be disclosed in accordance with the Privacy Act System of Records, 77VA10Q.

(2) The clinical pharmacist with a scope of practice should be provided with a written list of the clinical practice evaluation indicators that are to be reviewed prior to the start of the first professional practice evaluation period, and any time the indicators are changed.

(3) The criteria for the professional practice evaluation process is defined in advance, using objective criteria accepted by the clinical pharmacy program, recommended by the Chief of Pharmacy Services, the clinical service chief of alignment (as appropriate), and the ECMS, and approved by the medical facility Director, in alignment with the medical staff process.

(4) The use of triggers that may result in further intervention, should also be communicated to and accepted by the clinical pharmacist prior to the first professional practice evaluation, and any time these triggers are changed.

(5) The Chief of Pharmacy Services and clinical service chief of alignment (as appropriate), provide oversight of the clinical pharmacist's professional practice evaluation process for all clinical pharmacists with a scope of practice. The results of the professional practice evaluation are documented and reported with recommendations to the ECMS, for consideration in making the recommendation to the medical facility Director for final decision and approval.

(6) The process for professional practice evaluations must be ongoing throughout the year and provide the necessary information required for credentialing and oversight of the scope of practice for the clinical pharmacist.

(7) The patient care evaluation or clinical care review component of the professional practice evaluation is performed by a clinical pharmacist peer with similar scope and responsibilities. A clinical pharmacist from another VA medical facility may also be considered. Where the clinical pharmacist is aligned with a clinical service or a clinical pharmacist peer is not available, a physician or other licensed independent provider in the designated practice area should be included in the review.

(8) Professional practice evaluation reviewers should be rotated, whenever possible, to eliminate sources of personal bias.

(9) Professional practice evaluation leveling may be determined at the discretion of the local VA medical facility.

NOTE: Numerical scores or averages may be used as an alternative to assigning levels in the clinical care review process. In the event that leveling is utilized, it is

encouraged that the leveling be slightly different from the protected peer review process to ensure that the two processes are easily distinguished from one another.

(10) Focused and ongoing professional practice evaluations will occur at the local VA medical facility level for all clinical pharmacists with a scope of practice:

(a) Focused Professional Practice Evaluation. FPPE is a process whereby the Chief of Pharmacy Services, and clinical service chief of alignment (as appropriate), evaluates the pharmacist-specific competence of a clinical pharmacist who does not yet have documented evidence of competently performing the requested scope of practice at the VA medical facility. This is a time-limited period, defined by the ECMS, during which the clinical pharmacist's professional performance is assessed. A FPPE is required for all clinical pharmacists immediately following the approval of an initial scope of practice, when a clinical pharmacist has had a lapse in clinical activity, and when duties expand beyond what is authorized in the current scope of practice. During the FPPE competency should be assessed in relation to the clinical pharmacist's ability to perform the functions outlined in the scope of practice requested. The FPPE is not a restriction or limitation on the clinical pharmacist's ability to practice autonomously but is an opportunity for the clinical pharmacist to demonstrate the requisite skill and knowledge, and may include remediation (such as additional training or mentorship). The results of the FPPE must be documented in the clinical pharmacist's profile and reported to the ECMS for consideration in making recommendation on scope of practice and other considerations.

1. An initial FPPE is required for all clinical pharmacists at the time of initial appointment with a scope of practice or when duties expand beyond what is authorized in the current scope of practice. An initial FPPE can be accomplished through evaluation of training, experience, previous review of scope of practice held, and references.

2. A second use of the FPPE when a clinical pharmacist has had a lapse in clinical activity, as recommended by ECMS.

3. The FPPE allows the clinical pharmacist to continue practicing autonomously while an assessment is being accomplished and at the same time, assure that the patients are receiving quality, safe care.

4. All decisions relating to the Clinical pharmacist's scope of practice should be made in conjunction with the Chief of Pharmacy Services, clinical Service Chief, as applicable, and the ECMS.

(b) Ongoing Professional Practice Evaluation. OPPE is the ongoing monitoring process for scope of practice oversight of the clinical pharmacist to confirm the quality of care delivered and ensure patient safety. The OPPE process allows the clinical leadership to identify professional practice trends that affect quality of care and patient safety, some of which may require intervention. Data must be pharmacist specific, reliable, easily retrievable, timely, justifiable, comparable, and risk adjusted where appropriate. The OPPE process should include the following elements:

1. The time frame for OPPE should be consistent with the locally defined processes. It is suggested that, at a minimum, the Chief of Pharmacy Services, and if appropriate, clinical service chief of alignment, must be able to demonstrate that relevant practitioner data is reviewed on a regular basis (i.e., at least biannually).

2. Any patient care concerns that arise from the OPPE should be addressed immediately by the Chief of Pharmacy Services, and if appropriate, clinical service chief of alignment. When a clinical concern has been identified from the OPPE process or other review process, the supervisor must act respond appropriately to complete a fact finding and follow processes outlined in VA Handbook 5013 or VA Handbook 5021, as applicable, or subsequent policy issue, to determine if the clinical concern (s) is substantiated. In the event that the fact finding consists of a focused clinical care review, it must include a review of the pharmacist's practice that is completed by an appropriate peer. Any required actions or concerns must be reported to ECMS, as appropriate. .

3. The results of OPPE are used at the time of re-credentialing and renewal of a clinical pharmacist's scope of practice. Results of clinical pharmacist's professional practice evaluations, triggered or on-going reviews, must be documented in the clinical pharmacist's profile and reported to the ECMS for consideration in making recommendation on scope of practice.

4. The Chief of Pharmacy Services must review, on an ongoing basis, all professional practice evaluation activities for clinical pharmacists with a scope of practice and must provide reports to the ECMS, as appropriate.

c. **Protected Peer Reviews.** Protected peer reviews are performed for quality management and overseen at the local facility level by the appropriate authorizing committee. Clinical pharmacists undergo protected peer reviews as a component of the quality assurance process as defined in VHA Directive 2010-025, Peer Review for Quality Management, or subsequent policy issue. The authority for Peer Review for Quality Management (Protected Peer Review) is 38 U.S.C. 5705 and its implementing regulations Title 38 Code of Federal Regulations (CFR) 17.500 through 17.511.

18. STAFFING STANDARDS:

a. **Staffing Ratios for Clinical pharmacists.** The appropriate ratio of Clinical pharmacists is generally left to the individual facility based on patient care needs, program needs, and availability of resources. The staffing standards, described in the following paragraphs 18.b. through 18.e., are current recommendations; however, variations may exist at the local level and are subject to change as new, more robust methods to determine staffing ratios become more common. Appropriate ratios depend on the role of the clinical pharmacist in comprehensive medication management, staffing support, and role and responsibilities within the program.

b. **PACT Ratios.** PACT staffing must be sufficient to ensure that all patients assigned to the patient panel receive appropriate and desired health care. It is recommended there be at least 1.0 Full-time Equivalent (FTE) employee for a clinical

pharmacist with a scope of practice for every three patient panels (approximately 3600 patients) as described in VHA Handbook 1101.10, Patient Aligned Care Teams (PACT). The PACT clinical pharmacist assists teamlets and patients with comprehensive medication management and disease management services including, but not limited to, diabetes, hypertension, hyperlipidemia, and other chronic disease management services. The PACT clinical pharmacist with a scope of practice is integral to manage patients who have not reached or are not maintaining the intended therapy goals and those with medical conditions which are costly and associated with the use of multiple medications (e.g., cardiovascular disease, COPD, cancer chemotherapy, depression, and hypothyroidism). Staffing ratio may be adjusted upward locally to provide appropriate clinical pharmacy services.

c. **Anticoagulation Ratios.** When possible, anticoagulation clinics should remain centralized as existing literature documents improved efficacy and safety of these services provided in a centralized anticoagulation clinic compared to usual care in the typical primary care setting. It is recommended that there be at least 1.0 FTE for an anticoagulation clinical pharmacist with a scope of practice for every 5 patient panels (approximately 6000 patients) as described in VHA Handbook 1101.10, Patient Aligned Care Teams (PACT). The staffing for the anticoagulation clinical pharmacist should be in addition to the PACT clinical pharmacist. It is important to note that these ratios were created as a guide. Staffing ratio may be adjusted upward locally to provide appropriate pharmacy-related care to patients. In addition, factors such as lack of ancillary support staff for appointment management, laboratory monitoring of International Normalized Ratios (INRs), telephone triage, and other non-clinical features of anticoagulation management may lead to a requirement for a higher staffing ratios in this area.

d. **Home-Based Primary Care.** A Home-based Primary Care (HBPC) interdisciplinary team consists of specified staff, each with sufficient dedicated time for HBPC as part of their position description or functional statement. The clinical pharmacist is integral to patient care and recommended per VHA Handbook 1141.01, Home Based Primary Care Program. Caseload is to be determined locally as it is dependent on many factors. There are designated roles and responsibilities for the HBPC clinical pharmacist to include performing initial and subsequent periodic assessments of medication therapy (minimum of every 90 days) to identify patient-specific medication issues including drug interactions, adverse effects, efficacy, appropriateness, and compliance problems, with monitoring as appropriate. In addition, the clinical pharmacist has a role in the interdisciplinary team meetings and rounds, post-fall medication assessment, as well as serving as the medication expert for the team and Veterans. There is currently little validated information available regarding the time required to perform the activities related to the HBPC clinical pharmacist's responsibilities, however a review of services within VHA provided guidance as to appropriate staffing ratios for HBPC. Based on the results of a case management and productivity workgroup survey, it is recommended to have at least 1.0 clinical pharmacist FTE (working at least 190 hours per month) for each 100 HBPC patients just to conduct the mandatory requirements. Additional staffing support is necessary to conduct the other activities as described in VHA Handbook 1141.01 to include comprehensive medication management defined in the clinical pharmacist's scope of

practice and dependent on pharmacy service support available as described in the HPBC Pharmacist Project located at

<http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/HPBC.aspx>. **NOTE:** *This is an internal VA Web site and is not available to the public.*

e. **Other Specialty Areas.** Staffing ratios for clinical pharmacists may differ at each VA medical facility based on program needs, resources available, and role of the clinical pharmacist in the program area. VHA has identified a number of patients with unmet needs in areas such as Osteoporosis, Hepatitis C and Antimicrobial Stewardship in which a clinical pharmacist can play a key role if available full-time or part-time. In VHA Handbook 1162.02, Mental Health Residential Rehabilitation Treatment Program (MH RRTP), there are designated roles and responsibilities as well as staffing ratios for the clinical pharmacist in Mental Health Residential Treatment Programs. In VHA Directive 1031, Antimicrobial Stewardship Programs (ASP), an Antimicrobial Stewardship Pharmacy Champion should be identified and actively involved in defined components and support stewardship initiatives at the facility level. Staffing ratios may be adjusted upward locally to provide appropriate comprehensive medication management. **NOTE:** *Staffing model guidance can be found on the Clinical Pharmacy SharePoint at <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/default.aspx>. This is an internal VA Web site and is not available to the public.*

19. WORKLOAD CAPTURE AND PHARMACY METRICS:

a. **Overview.** Clinical pharmacists within VHA are recognized as leaders in the provision of comprehensive medication management services. It is imperative that VHA clinical pharmacists document the type and volume of their interventions for VHA workload, resource allocation, and to advance the recognition of pharmacist professional services. VHA pharmacy clinics should use the 160 stop code in the primary or secondary position when clinical pharmacy services are provided.

(1) Services offered by clinical pharmacists include clinical interventions such as disease management, comprehensive medication management for multiple disease states and conditions, medication therapy management, and medication consultation.

(2) These encounters require proper documentation according to national policies that include, but are not exclusive to, Decision Support System (DSS) and Health Information Management System (HIMS). All patient care encounters made by the clinical pharmacist that includes a medical history and clinical decision-making can be documented as count workload.

(3) Clinical pharmacy patient care encounters may involve direct patient interaction or may involve formal consultation utilizing information available in CPRS without a face-to-face encounter with the patient (e.g., chart consult, E-Consults).

b. **Workload capture.** Outpatient and inpatient pharmacy clinics are set up using DSS identifiers, or stop codes. All clinical pharmacy clinics operating under the oversight of the pharmacy service should be given a primary stop code indicative of pharmacy (i.e., 160 stop code) when the clinical pharmacist is the main clinical provider

responsible for that patient care encounter whenever possible. Secondary stop codes should be used to further define the primary workgroup or practice setting. There may be identified issues that require facilities to change the primary stop code from 160 to another code. If this occurs, it is imperative that the 160 stop code be used in the secondary position. Clinical pharmacy patient care encounters include, but are not limited to, disease management, comprehensive medication management, medication therapy management, and clinical chart consultation. Encounters can occur in both the outpatient and inpatient setting regardless of practice area or location (e.g., mental health, primary care, acute care) and should encompass at a minimum three elements: history taking, clinical decision making, and documentation in the medical record. Documentation and generation of clinical pharmacy patient care encounters may be provided by all levels of licensed pharmacists to include those with and without a scope of practice. In addition, it may be appropriate to ensure pharmacy clinics have the appropriate clinic set-up to include CHAR4 codes, as applicable. **NOTE:** A complete list of DSS and CHAR4 codes are provided on the DSS Web site at http://vaww.dss.med.va.gov/programdocs/pd_oident.asp. **NOTE:** This is an internal VA Web site and is not available to the public. Clinical pharmacy clinic set-up should be in accordance with PBM guidance and workload capture information found on the Clinical Pharmacy SharePoint at: <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Workload%20Capture.aspx>. **NOTE:** This is an internal VA Web site and is not available to the public.

c. **Clinical Pharmacy Metrics and Tools.** Clinical pharmacists should have access, as appropriate, to the databases and tools to perform population management and high-risk patient identification. This includes identification of patients in need of comprehensive medication management, as well as patients that may be identified as being over-treated or experiencing adverse drug reactions.

20. PROFESSIONAL COMMITMENT EXPECTATIONS:

a. **Research and Quality Improvement Projects.** Clinical pharmacists should participate, support, and promote health services research involving clinical pharmacy practice. All clinical pharmacists should work with their local facilities to develop research and quality improvement projects that accurately reflect the importance of the role of clinical pharmacists in the health care team, as appropriate.

b. **Trainees.** The education and training of health professions trainees is one of VA's four missions. In accordance with this mission, the PBM CPPO fully supports the establishment of coordinated programs and activities at all VA medical facilities in partnership with affiliated local and national academic institutions. The Office of Academic Affiliations (OAA) supports pharmacy education training and programs including pre-doctoral pharmacy internships, post-doctoral residencies and fellowships, and other professional training programs. Success of interprofessional collaboration has been noted to be dependent on factors such as building trust, establishing strong communication strategies, developing common aims, addressing power differences, and establishing organizational structures and processes that facilitate collaboration in the health care team. The Chief of Pharmacy Services has responsibility for ensuring

educational training programs are integrated into practice for all pharmacy staff. Clinical pharmacists should be integrated into training programs of allied health professionals, as well as other professionals available at the local VA medical facility level, as appropriate.

c. **Publications.** Clinical pharmacists are often involved at multiple levels with quality improvement projects, research, as well as providing valuable information regarding medication use, medication management, monitoring, and safety. It is important to the profession of clinical pharmacy practice that VA clinical pharmacists contribute to publications in peer-reviewed journals. Time permitting, all clinical pharmacists should work to assure that VHA leads the practice of clinical pharmacy in publishing clinical pharmacy research and its unique role in the pharmacy practice model.

d. **Professional Organization Involvement and Affiliations.** Professional organization involvement is essential to developing the role of the individual pharmacy professional as well as improving collaboration on issues facing the future of clinical pharmacy practice. It is the responsibility of each individual in the profession to lead the future of clinical pharmacy towards a role of practicing at the top of the licensure and scope for all clinical pharmacists. This includes involvement at leadership levels in professional organizations and societies at the national and local levels. The Chief of Pharmacy Services should promote clinical pharmacist involvement with key stakeholders and professional organizations both within pharmacy and the broader healthcare team. Each clinical pharmacist must be an advocate for the profession and seek to develop new and innovative roles for clinical pharmacy practice that will sustain the profession in the future.

21. NATIONAL PHARMACY BENEFITS MANAGEMENT (PBM) SUPPORT:

a. **Clinical Pharmacy Practice Office.** The CPPO was established by PBM in 2010. Its initiatives and efforts are led by the Deputy Chief Consultant for PBM Professional Practice and the Assistant Chief Consultant for Clinical Pharmacy Services and Healthcare Delivery Services Research. The CPPO, PBM key stakeholders, and its advisory committees seek to streamline VHA's clinical pharmacy program while developing standardized pharmacy practice models, educational initiatives, developing projects that assess the impact of clinical pharmacy interventions and penetration, as well as providing guidance on issues related to clinical pharmacy practice. The CPPO can be reached in the global address list in Outlook at [VHAPBH Clinical Pharmacy Practice Office \(CPPO\)](#).

b. **Clinical Pharmacy Advisory Board.** The Clinical Pharmacy Advisory Board (CPAB) serves as a field advisory board for the CPPO. The CPAB was founded in 2010 has made dramatic contributions to the evolution and transformation of clinical pharmacy practice in VA. The CPAB strives to address the challenges that face clinical pharmacy practice. The CPAB is dedicated to developing new and innovative areas of clinical pharmacy outcomes research while continuing to develop the pharmacy operations, technicians, and primary support systems. The CPAB membership consists

of designated VPEs, Chiefs and Associate Chiefs of Pharmacy, clinical pharmacy leaders, and clinical pharmacists. The CPAB goal is to create a transformational plan that will provide the basis for initiatives and the strategic plan for Clinical Pharmacy Practice Office.

c. **Clinical Pharmacy Executive Board.** The Clinical Pharmacy Executive Board (CPEB) serves as a field advisory board for the Clinical Pharmacy Practice Office. The CPEB was founded in 2012 to integrate pharmacy operations and planning with an expanded perspective of physician leaders and key individuals across various sections of PBM and VA. The CPEB focuses on VHA policy needs in the area of clinical pharmacy practice and patient centered care. The CPEB represents an interprofessional approach that will support and sustain transformation in clinical pharmacy practice for VHA.

d. **Clinical Pharmacy Practice SharePoint.** The Clinical Pharmacy Practice SharePoint serves as a centralized location for documents pertinent to clinical pharmacy practice. It is a clearinghouse for shared information related to PBM policy and guidance, local VA medical facility policies and tools, educational tools, and a resource for all clinical pharmacy practice. **NOTE:** Information can be accessed at: <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/default.aspx>. **NOTE:** This is an internal VA Web site and is not available to the public.

e. **Clinical Pharmacy SharePoint Specialty Sites.** The Clinical Pharmacy SharePoint Specialty Sites were created due to the overwhelming response from facility clinical pharmacists to create specialty sites specific to various clinical pharmacy program areas. These sites are managed by volunteer SharePoint managers from the various subspecialty areas. Information related to clinical pharmacy practice can be found on these specialty sites. For Specialty SharePoint managers, refer to the link found under Useful Links at: <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/default.aspx>. **NOTE:** This is an internal VA Web site and is not available to the public.

f. **National Clinical Pharmacy Practice Conference Calls.** The Clinical Pharmacy Practice Office provides clinical pharmacists with educational information on monthly national clinical pharmacy conference calls. Educational topics include clinical pharmacy practice elements in a variety of settings. Information, topic discussions, and resources discussed during monthly calls can be found on the Clinical Pharmacy SharePoint site located at: <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/National%20Clinical%20Pharmacy%20Conference%20Calls/Forms/AllItems.aspx>. **NOTE:** This is an internal VA Web site and is not available to the public.

g. **Clinical Pharmacy Practice Highlights.** A Clinical Pharmacy Practice Highlights was created in 2015 by the Clinical Pharmacy Practice Office to encompass issues related to clinical pharmacy practice. The newsletter can be accessed at <http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/The%20SCOPE%20%20PBM%20National%20Clinical%20Pharmacy%20Newslett/Forms/AllItems.aspx> **NOTE:** This is an internal VA Web site and is not available to the public.

h. **National Clinical Pharmacy Practice Council.** A National CPPC promotes sharing of information amongst clinical pharmacy services within VA. The National CPPC is aligned with the principles described paragraph 9 of this Handbook. It assists pharmacy leaders in ensuring proper alignment of clinical pharmacy practice components. **NOTE:** *Resources for the CPPC can be accessed at the following SharePoint link:*
<http://vawww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Clinical%20Pharmacy%20Practice%20Council.aspx>. **NOTE:** *This is an internal VA Web site and is not available to the public.*

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ACRONYMS USED IN THIS HANDBOOK

Acronym	Term
CBOC	Community-based Outpatient Clinic
CFR	Code of Federal Regulations
CLC	Community Living Centers
CPPC	Clinical Pharmacy Practice Council
CPRS	Computerized Patient Record System
CPAB	Clinical Pharmacy Advisory Board
CPEB	Clinical Pharmacy Executive Board
CPPO	Clinical Pharmacy Practice Office
CPT	Current Procedural Terminology
DEA	Drug Enforcement Administration
DSS	Decision Support System
ECMS	Executive Committee of the Medical Staff
FDA	Food and Drug Administration
FPPE	Focused Professional Practice Evaluation
FTE	Full-time Equivalent (employee)
HBPC	Home-based Primary Care
HIPAA	Health Insurance Portability and Accountability Act
KSA	Knowledge, Skills, and Abilities
INR	International Normalized Ratio
OPPE	Ongoing Professional Practice Evaluation
P&T	Pharmacy and Therapeutics Committee
PACT	Patient Aligned Care Team
PBM	Pharmacy Benefits Management Service
PGY1	Post-Graduate Year 1
PGY2	Post-Graduate Year 2
PCC	Person Class Code
OAA	Office of Academic Affiliations
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems Technology Architecture
VPE	VISN Pharmacy Executive

CLINICAL PHARMACIST SCOPE OF PRACTICE**Clinical pharmacist Scope of Practice
Statement for Comprehensive Medication
Management**

1. PROFESSIONAL QUALIFICATIONS: The clinical pharmacist is trained in clinical pharmacy practice and comprehensive medication management to include, but not limited to clinical pharmacokinetics, therapeutics, and clinical pharmacology. A clinical pharmacist has the unique mix of knowledge, skills, and abilities in addition to education, training and experience to function under a scope of practice. The clinical pharmacist has a current unrestricted pharmacist license and is in good standing with the pharmacist's licensing body.

2. CLINICAL FUNCTIONS:

a. The clinical pharmacist with a scope of practice is an individual in a highly specialized practice area in which there is documented evidence of knowledge, skills, and abilities based on the individual clinical pharmacist's education, training, and experience. The scope of practice as part of collaborative medication management, allows the clinical pharmacist to function with a high level of autonomy and independent clinical decision-making for activities included in the scope of practice and collaboratively with the health care team for the overall care of the Veteran. The clinical pharmacist is responsible and accountable for the disease states and conditions managed under the clinical pharmacist's scope of practice. Prescribing, administering or dispensing controlled substances may be included in the scope of practice only if the clinical pharmacist is authorized by their state license to do so and complies with the limitations and restrictions on that authority.

b. The clinical pharmacist is responsible for evaluating medication therapy through direct patient care assessment. Through clinical assessment, the clinical pharmacist relates patient responses to medication therapy, communicates and documents those findings, makes recommendations to appropriate individuals and in appropriate records, and implements and monitors pharmacotherapeutic care plans. It is expected that the minimum Primary Care practice areas encompass the medication management of patients with chronic diseases including, but not limited to, diabetes, hypertension, hyperlipidemia, and anticoagulation. The clinical pharmacist with a scope of practice is responsible for the decisions made under their scope of practice. This includes the selection of the most appropriate medication for disease state management, monitoring of patient outcomes, analysis of adverse drug events and medication reconciliation. The clinical pharmacist's non-direct patient care activities include formulary management, teaching and research (as applicable), quality assurance, medication utilization review and staff development.

c. A clinical pharmacist with a scope of practice can perform all duties that are considered routine of a clinical pharmacist without a scope of practice. The clinical pharmacist with a scope of practice will work in concert with the health care team in

their assigned practice area. The Chief of Pharmacy Services and clinical service chief of alignment ensure the clinical pharmacist scope of practice aligns with the medical staff process as defined in the facility bylaws. A clinical pharmacist with a scope of practice may carry out functions in their advanced practice role, under an approved scope of practice, to include:

(1) Executing therapeutic plans utilizing the most effective, safest, and most economical medication treatments.

(2) Ordering, subsequent review, and action on appropriate laboratory tests and other diagnostic studies necessary to monitor, support, and modify the patient's drug therapy.

(3) Prescribing medications, devices, and supplies to include: initiation, continuation, discontinuation, monitoring and altering therapy.

(4) Performing the physical measurements and objective assessments necessary to ensure the patients appropriate clinical responses to drug therapy.

(5) Ordering medications, patient care supplies, and vaccines as necessary for the provision of pharmaceutical care.

(6) Identifying and taking specific corrective action for drug-induced problems according to protocol, procedure, guideline or standard of care.

(7) Ordering consults (e.g., dietician, social work, specialty provider), as appropriate, to maximize positive drug therapy outcomes.

(8) Providing clinical pharmacy expertise, comprehensive medication management and monitoring for practice-based areas to include clinics and wards in conjunction with the attending physician or team (e.g., Home-based Primary Care, Internal medicine, critical care, Community Living Centers).

(9) Obtaining and documenting informed consent for treatments and procedures for which the clinical pharmacist is responsible. The clinical pharmacist Scope of Practice authorizes the ability to obtain informed consent for the treatment or procedure being performed including those circumstances in which the clinical pharmacist is the prescriber of a treatment that requires consent or when they are providing medication management services on behalf of the original prescriber. **NOTE:** *The clinical pharmacist must have sufficient knowledge and training in the treatment or procedure, its indications, risk and benefits, complications, and alternative treatments, to effectively counsel the patient.*

(10) Clinical pharmacists with a scope of practice may prescribe controlled substances only if authorized by the facility and the state of licensure (i.e., the statutes and regulations that defines the terms and conditions of the pharmacist's license) and they perform this function in accordance with Federal law and regulations and VHA

Policy. **NOTE:** The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 defines requirements for the prescription of controlled substances (Schedules I through V as defined under the Controlled Substances Act) via telemedicine. Questions regarding the authority under the Ryan Haight Act should be directed to VHA TeleHealth Services at <http://vaww.telehealth.va.gov/about/contact.asp>. All prescribers of controlled substances must ensure compliance with the regulations of this Act and all applicable Federal law and VHA policy.

3. APPLICANT REQUEST:

a. In completing an application for the aforementioned scope of practice, I agree to abide by the policies and procedures set forth by the VA medical center and all applicable practice standards within my scope. I will limit my performance to the boundaries described and within the functions requested. I certify that I am qualified and competent to perform the functions as requested.

b. The professional practice evaluation results will be reviewed at least biannually by the ECMS and Chief of Pharmacy Services and amended when necessary to reflect changes in the clinical pharmacist's duties and responsibilities and/or medical center policy.

4. REFERENCE: Academy of Managed Care Pharmacy. Sound medication therapy management programs, version 2.0 with validation study (Journal of Managed Care Pharmacy.2008; 14:(1 Suppl B):S2-S44).

5. COLLABORATION: The clinical pharmacist with a scope of practice functions as a health care provider with a high level of autonomy and exercise independent decision making within their scope of practice. A collegial relationship with mutual consultation and referral exists with the collaborating provider(s) and the clinical pharmacist with a scope of practice. Consultation with a physician or appropriate provider is required for advanced patient care management beyond the applicant's scope of practice, when changes occur in the patient's condition, and when referrals to higher levels of care are required as outlined in medical center policy. A collaborating provider(s) is available at all times by telephone or in person for consultation.

6. SCOPE OF PRACTICE:

Part 1. General area of responsibility for activities to be performed under the scope of practice (must choose at least one):

- ☐ Medical center
- ☐ Community Based Outpatient Clinic
- ☐ Contracted locations
- ☐ Domiciliary

☐ Telemedicine (or Teleconsultation) within the HealthCare System and at designated locations in accordance with facility processes (specify any locations outside of the main facility below):

☐ Other location (specify below):

Part 2. The clinical pharmacist scope of practice includes the following practice areas or diseases or conditions (must choose at least one)

☐ Comprehensive Disease State Management, inpatient

☐ Internal Medicine

☐ Specialty Care such as surgery, infectious disease, critical care, community living centers, psychiatry, hematology/oncology, etc. (define specialty):

☐ Focused Scope for the following diseases/conditions in the inpatient setting:

☐ Comprehensive Disease State Management, outpatient

☐ Primary Care

☐ Specialty Care such as infectious disease, cardiology, mental health, hematology/oncology, etc. (define specialty):

☐ Focused Scope for the following diseases/conditions in the outpatient setting:

CLINICAL PHARMACIST MENTORSHIP

a. A clinical pharmacist mentorship is an optional period of training and observation in which a currently employed clinical pharmacist is assigned a “mentor” to provide additional training to obtain necessary competencies for new or expanded clinical functions. A mentorship is not a requirement for all clinical pharmacists to obtain a scope of practice, but is an option that may occur prior to approval of an initial or revised scope of practice. The mentorship will differ based on the individual clinical pharmacist’s competency for the activities outlined in their scope of practice and will be individualized based on need.

b. Mentorship of a clinical pharmacist will typically occur in situations where the clinical functions outlined in their functional statement will change. A mentorship may be warranted if there is insufficient evidence the clinical pharmacist’s readiness to take on duties outlined in their proposed scope of practice based on the individual clinical pharmacist’s competency assessments, education, training, and experience in the practice area.

c. A mentorship is required for:

(1) Any currently-employed clinical pharmacist with less than one year of post-graduate experience (e.g., graduated within the last year) who requests an initial scope of practice; or

(2) Any clinical pharmacist requesting an initial or expanded scope of practice in a specialized practice area in which there is not sufficient evidence of their readiness to perform these activities based on the individual clinical pharmacist’s education, training, and experience. **NOTE:** *An example includes a Clinical pharmacist who has completed a post-graduate year 1 residency and has 2 years of experience with a scope of practice in primary care (collaborative medication management scope of practice for primary care). This individual is applying for a new scope of practice in Hepatitis C and does not have past clinical pharmacy practice experience in this area. In this scenario, a mentorship would be recommended prior to approval of this additional practice area in their scope of practice.*

d. When appropriate, a mentorship must adhere to the following principles:

(1) Every clinical pharmacist participating in a mentorship must be evaluated by an observation of a minimum number of patient care encounters and chart reviews. At a minimum, during the mentorship the clinical pharmacist should be directly observed in the practice setting during patient care encounters for a period of 20 full work days and with a minimum review of at least 50 patient care encounters. The mentorship time frame should be sufficient to assess the competency for the clinical pharmacist to perform at the highest level of clinical practice under a scope of practice and may differ based on the education, training, and competency of the individual clinical pharmacist. The time frame and numbers may be determined locally, as long as the minimums are

addressed. The mentorship may be extended if there is not adequate evidence of competency after the initial time frame.

(2) Every clinical pharmacist participating in a mentorship is assigned a “mentor” by the Chief of Pharmacy Services and if appropriate, clinical service chief of alignment. The “mentor” must be an experienced individual (preferably a clinical pharmacist with a scope of practice) who provides clinical guidance and assistance to an assigned clinical pharmacist undergoing mentorship. In the event a suitable clinical pharmacist mentor cannot be identified, any individual with a similar or higher level scope of practice (or privileges if another profession) as the individual under consideration may be utilized.

(3) The mentorship evaluation, and review of patient cases, should mirror the clinical indicators and measures outlined in the professional practice evaluation program for a clinical pharmacist with a similar scope of practice.

(4) The assigned mentor will provide recommendations as to the clinical pharmacist’s readiness for a scope of practice or if the mentorship should be extended; however, the Chief of Pharmacy Services and if appropriate, clinical service chief of alignment, makes the final determination on whether to endorse the clinical pharmacist’s application for a scope of practice.

(5) The mentorship results, in addition to all other required elements for scope of practice outlined in paragraph 15, must be included in the scope of practice application, to demonstrate the clinical pharmacist’s readiness for a scope of practice in the defined practice area.